ET 05-331
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Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)
	)
Respironics, Inc. Petition for Waiver	)
of Section 15.205(a) of the	)
Commission's Rules	)
	)

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Federal Communications Commission
Office of Secretary

PETITION FOR WAIVER

Respironics, Inc. ("Respironics"), by its undersigned attorneys and pursuant to Section 1.3 of the Commission's rules, hereby seeks a waiver of Section 15.205 of the Commission's rules with respect to its "ActiReader" devices, which are part of activity monitor systems used by medical researchers and other staff. As explained below, while the ActiReader does not comply with the technical requirements of Section 15.205(a) because its fundamental frequency of operation is within a restricted band, the actual radiated energy within the band is far below the limits for spurious emissions by intentional radiators. Accordingly, the ActiReader does not pose a risk of harmful interference to licensed or other primary services within the 90-110 kHz restricted band and, therefore, does not threaten the "primary purpose" of the Part 15 rules.

Given the importance of the medical research being performed using the ActiReaders and the lack of adequate alternatives in the market, Respironics requests a waiver of the Commission's rules with respect to existing ActiReaders and to continue to manufacture and sell a defined number of ActiReaders for a limited time while it redesigns the ActiReader to comply with the Commission's rules. Specifically, Respironics requests a waiver of Section 15.205(a) of the Commission's rules with respect to approximately 1,500 ActiReaders currently in the field and an additional

approximately 1,000 ActiReaders that are expected to be shipped in the next 18 months, which is how long it will take Respironics to redesign and produce ActiReaders that are fully compliant with the Commission's rules.

I. INTRODUCTION AND BACKGROUND

Respironics is a leading developer, manufacturer, and distributor of products and programs that manage sleep disordered breathing, chronic obstructive pulmonary disease, asthma, allergies and sinusitis, infant jaundice and apnea, heart failure and restrictive lung disorders. Founded in 1976, Respironics is a publicly-held company that markets its products in over 125 countries and employs more than 4,000 people worldwide.

In April 2005, Respironics acquired Mini-Mitter Company, Inc. ("Mini-Mitter"), a privately-held company located in Bend, Oregon that develops and sells sleep and physiological monitoring products to commercial sleep laboratories and other medical, pharmaceutical, and health research institutions involved in clinical trials. Among Mini-Mitter's products are a series of activity monitor products used to monitor sleep patterns, physical activity/calorie expenditures, and a variety of related indicia of human activity and behavior. Use of these products involves coupling a measuring device (such as a watch in the ActiWatch[1] family of products) to a clinical subject, logging activity data, and downloading the data to a computer for analysis. The data is downloaded from the measuring device using an accessory device known as the ActiReader, which in turn is connected to a PC using an RS-232 serial cable. To perform a data download, a user

[1] The ActiWatch is the most common activity monitoring device that is used in conjunction with the ActiReader. The ActiWatch is worn on the wrist by a patient/subject, and is equipped with a highly sensitive accelerometer as well as the ability to record data from a second sensor. The ActiWatch can generate an activity record that can be used to study sleep/wake patterns, sleep disorders, circadian rhythm disorders, basic activity levels, etc. The data contained in such a record is downloaded to a PC by coupling the ActiWatch to an ActiReader.

couples the ActiWatch or other measuring device to the ActiReader, which downloads the data via a low-power, short-range wireless link. The wireless link is between the ActiReader and the measuring device and is only active when the latter is coupled to the former. At present, there are approximately 1,500 ActiReader devices in the field in clinics, hospitals, and research labs.

Soon after acquiring Mini-Mitter, Respironics discovered that the ActiReader had not been authorized pursuant to Part 2 and Part 15 of the Commission's rules. Moreover, Respironics also discovered that the ActiReader was not in compliance with the technical requirements set forth in Section 15.205(a) of the Commission's rules because the fundamental frequency at which it operates was 104 kHz (*i.e.*, within the 90-110 kHz frequency band in which only spurious emissions are allowed).[2] Respironics promptly contacted counsel and began the process of redesigning the ActiReader/ActiWatch family of products so as to comply with the Commission's rules. However, given the number of medical researchers and related personnel who use the ActiReader and related products, and the time it will take to develop and produce a new product, Respironics seeks a waiver of the Commission's rules to permit the continued use of existing ActiReaders and the production and sale of an additional 1,000 ActiReaders over the next 18 months.

II. GRANT OF A WAIVER IS SUPPORTED BY GOOD CAUSE BECAUSE PERMITTING THE PRODUCTION AND SALE OF ACTIREADER DEVICES WOULD FURTHER THE PUBLIC INTEREST WITHOUT POSING A RISK OF INTERFERENCE

Waiver of the Commission's rules is permitted upon a showing of "good cause."[3] The Commission may exercise its discretion to waive a rule "where particular facts

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2 47 CFR 15.205(a).

3 47 CFR § 1.3.

would make strict compliance inconsistent with the public interest."[4] The Commission has noted that in order to be granted a waiver, an applicant must show that "any benefits achieved by its proposal are in the public interest and that a waiver would not compromise the fundamental policies served by the rule."[5] As explained below, good cause exists for waiver of the rules because grant of a waiver will serve the public interest in important medical research while not compromising the fundamental purpose served by the rule — *i.e.*, prevention of interference.

A. The ActiReader Devices Pose No Risk of Interference to Licensed or Other Primary Services

While the ActiReader devices are in technical violation of Section 15.205(a) of the rules, they comply with the spirit of the rules and do not pose a threat of interference to licensed or other primary operations. The radiated emissions from the ActiReader are well below the radiated emission limits for intentional radiators specified in Section 15.209 of the Commission's rules.[6] In fact, at most frequencies, the radiated emissions are below the noise floor of typical measurement systems.[7] The ActiReader does not meet the specifications of Section 15.205(a) only because the radiated emissions at 104 kHz are at a fundamental frequency of operation; had the emissions been spurious, they would have been well under the prescribed limit (by a margin of approximately 50 dB).[8] Because other devices operating within the 90-110 kHz restricted band (*i.e.*, devices the Part 15 rules are designed to prevent interference with) are affected only by radiated

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[4] Northeast Cellular Tel. Co. v. FCC, 897 F. 2d 1164, 1166 (D.C. Cir. 1990) (citing WAIT Radio v. FCC, 418 F.2d 1153, 1159 (D.C. Cir. 1969)).

[5] *Midwest Communications, Inc.*, 7 FCC Rcd 159, 160 (1991).

[6] *See* Exhibit 1, providing details of radiated spurious emissions for the ActiReader based on a technical study performed by Advanced Compliance Solutions, Inc., FCC Registration No. 89450.

[7] *See id.*

[8] *See id.*

emissions levels and not whether the emissions are spurious or not, the ActiReaders pose no greater interference risk than any of the presumably thousands of unlicensed devices that radiate spurious emissions in the 90-110 kHz restricted frequency band.

The purpose and functioning of the ActiReader further explains the extremely low power at which it operates. The ActiReader radiates RF energy over a very short range only when a measuring device such as an ActiWatch is coupled to it, and only for the purpose of downloading data from the coupled measuring device. Thus, unlike many Part 15 devices such as Wi-Fi transmitters, garage door openers, baby monitors, etc., which radiate RF energy over ranges of 10 feet or more, the range of the ActiReader's radiated emissions is no more than a few millimeters — just enough to communicate with the coupled device from which the data is downloaded. Because the ActiReader emits energy over such a short range and only for the purpose of downloading data from a coupled measuring device, Respironics believes that the ActiReader complies with the spirit of the Commission's rules in that the ActiReader and measuring device, taken together, resemble an unintentional radiator since the generated RF energy is for use within the coupled devices.[9] This feature puts the ActiReader in a different category from many other Part 15 intentional radiators that are designed to transmit RF energy to a remote receiver.

Moreover, unlike Part 15 devices such as Wi-Fi transmitters or baby monitors, ActiReaders radiate RF emissions rarely and for very short periods of time. The emissions occur only when a measuring device such as an ActiWatch is coupled to the ActiReader, and only as long as it takes to download data from the measuring device. In

[9] *See* 47 CFR § 15.3(z) (defining an unintentional radiator as "[a] device that intentionally generates radio frequency energy for use within the device ....").

practice, this means that an ActiReader's extremely low power emissions typically occur once a day or even once every few days, and for only a few seconds each time.

Finally, a further reason why ActiReaders do not pose an interference threat is the environments in which they are used. Unlike many other Part 15 devices that end up in the hands of consumers, ActiReaders are used in controlled settings such as hospitals, sleep clinics, research labs, etc., where they are used by trained personnel. While measuring devices such as ActiWatches may be used in non-controlled settings (since they are worn by patients/subjects), they do not emit RF energy. As discussed above, the RF emissions occur only during the downloading of data when the measuring devices are coupled to the ActiReaders, and this only occurs in controlled, non-residential environments.[10] The Commissions rules governing unlicensed devices have long recognized the greater interference potential of devices used in residential settings by consumers over those devices used in non-residential environments by trained personnel.[11]

To summarize, while the ActiReader does not comply with the technical requirements of Section 15.205(a) because its fundamental frequency of operation is within a restricted band, the actual radiated energy within the band is far below the limits

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[10] If needed, as a further precaution, Respironics could include warning labels that the ActiReader is not to be used in residential environments. In addition, in keeping with past waiver grants, Respironics proposes that the ActiReader will be labeled with the following statement: "This equipment is authorized under a waiver issued by the FCC. If it is determined that the operation of this equipment has caused harmful interference to other radio operations, the operator shall immediately contact Respironics, Inc. at [phone number]." *See, e.g.*, Letter from Dale Hatfield, Chief, OET, to David E. Hilliard, Counsel to Time Domain Corp., June 29, 1999, at 2 (granting a waiver of Section 15.205(a) of the FCC's rules to Time Domain for operation of an UWB transmitter) ("Time Domain Waiver").

[11] For example, see the different treatment under Part 15 of Class A Digital Devices, which are "marketed for use in a commercial, industrial or business environment," and Class B Digital Devices, which are "marketed for use in a residential environment ...." 47 CFR § 15.3(h), (i).

for spurious emissions by intentional radiators.[12] Thus, the ActiReader poses no threat of interference to radio operations within the 90-110 kHz restricted band, and thereby does not threaten the "primary purpose" of the Part 15 rules.[13]

B. The Continued Operation of ActiReader Devices Serves the Public Interest

Waiver of Section 15.205 of the Commission's rules with respect to the ActiReader will serve the public interest by permitting the continued use of these devices in important medical research across the country. As discussed above, along with associated activity monitoring products such as ActiWatches, ActiReaders are used to study sleep/wake patterns, sleep disorders, circadian rhythm disorders, basic activity levels, etc. Such studies can be used for treatment and research in a variety of important therapeutic and scientific areas, including sleep medicine, pain monitoring, sports medicine, infectious disease research, clinical trials, obesity research, and depression. Many of these areas of medical research are of vital importance to the United States and global population. Research and treatment in these areas would be hurt if researchers and other medical professionals could not use the ActiReader and associated activity monitoring devices. The harm to research efforts will be particularly severe because there are no equivalent products on the market for researchers to use, meaning that researchers will not be able to simply redesign their research using different tools.

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12 47 CFR § 15.209.

13 *See* Time Domain Waiver at 3 (noting that "[p]reventing interference to other radio services is the primary purpose of the standards in Part 15."); *see also* Letter from Dale Hatfield, Chief, OET, to Ronald C. Labarca, U.S. Radar Inc., June 29, 1999 (granting a waiver of Section 15.205 of the FCC's rules to U.S. Radar for operation of a ground penetrating radar system, and noting that "[p]reventing interference to other radio services is the primary purpose of the standards in Part 15.") ("U.S. Radar Waiver"); Letter from Dale Hatfield, Chief, OET, to Terry G. Mahn, Counsel to Zircon Corp., June 29, 1999 (granting a waiver of Section 15.205 of the FCC's rules to Zircon for operation of a surface penetrating radar system, and noting that "[p]reventing interference to other radio services is the primary purpose of the standards in Part 15.") ("Zircon Waiver").

Approximately 1,500 ActiReaders are in the field, and an additional 1,000 ActiReaders are expected to be shipped to researchers in the next 18 months while the product is redesigned and the redesigned product is produced. This translates to several hundreds of researchers and medical personnel whose research and treatment of patients will be severely disrupted unless they can continue using the ActiReaders until they are redesigned. If a waiver is not granted, researchers and medical personnel will be forced to stop using not only the 1,500 ActiReaders currently in the field and the 1,000 that are expected to be shipped in the next 18 months, but also all the ActiWatches and other activity monitoring devices which rely on the ActiReader to download the data to be analyzed.[14]

C. The Petition for Waiver Is Supported By Good Cause

The discussion above demonstrates that a waiver of Section 15.205 of the Commission's rules is warranted with respect to the approximately 1,500 ActiReaders in the field at present and an additional 1,000 ActiReaders that are expected to be shipped in the next 18 months while the product is being redesigned. The importance of ActiReaders to research in a variety of therapeutic areas — from sleep disorders to depression to obesity — establishes that a waiver to permit their continued use is in the public interest. Moreover, and most significantly, the waiver is supported by good cause because the ActiReaders operate in controlled environments at extremely low power and for very short periods of time, thereby posing no threat of interference. The facts described above demonstrate that "strict compliance" with the Commission's rules is inconsistent the public interest in this case when the ActiReader poses no threat of

[14] There are approximately 12,000 ActiWatches in the field, with an additional 3,000 expected to be shipped in Fiscal Year 2006. All of these would be rendered useless if the data collected by them could not be downloaded, using ActiReaders, for analysis and research.

interference.[15] Similarly, grant of the waiver will not "compromise the fundamental policies" served by the Part 15 technical rules regarding radiated emissions, which is to prevent interference to licensed and other primary services.[16] Accordingly, Respironics has demonstrated good cause for a waiver of Section 15.205 of the Commission's rules because "benefits achieved by its proposal are in the public interest and . . . a waiver [will] not compromise the fundamental policies served by the rule."[17]

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Accordingly, and for good cause shown, Respironics respectfully requests a waiver of Section 15.205 of the Commission's rules to permit the continued use of ActiReaders that are currently in the field as well as production and sale of an additional approximately 1,000 ActiReaders over the next 18 months while the product is being redesigned.

Please do not hesitate to address any questions to the undersigned.

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15 *See* Northeast Cellular Tel. Co. v. FCC, 897 F. 2d 1164, 1166 (D.C. Cir. 1990) (citing WAIT Radio v. FCC, 418 F.2d 1153, 1159 (D.C. Cir. 1969)).

16 *See* Time Domain Waiver at 2; U.S. Radar Waiver at 2; Zircon Waiver at 1-2.

17 *Midwest Communications, Inc.*, 7 FCC Rcd 159, 160 (1991).

Respectfully submitted,

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EXHIBIT 1

7.2.4 Test Results

Table 7.2-1: Radiated Spurious Emissions

Frequency (kHz)	Level (dBuV) Pk	Antenna Polarity (H/V)	Correction Factors (dB)	Corrected Level (dBuV/m)	Limit (dBuV/m)	Margin (dB)	
Fundamental Frequency							
104	63.37	H	-94.80	-31.43	23.08	54.51	
104	67.25	V	-94.80	-27.55	23.08	50.63	
Spurious Emissions							
208	71.32	H	-96.50	-25.18	11.54	36.72	*
208	71.04	V	-96.50	-25.46	11.54	37.00	*
312	67.89	H	-96.80	-28.91	7.69	36.60	*
312	69.44	V	-96.80	-27.36	7.69	35.05	*
416	65.89	H	-97.00	-31.11	5.77	36.88	*
416	65.65	V	-97.00	-31.35	5.77	37.12	*
520	63.25	H	-57.10	6.15	46.15	40.00	*
520	63.25	V	-57.10	6.15	46.15	40.00	*
624	62.38	H	-57.10	5.28	38.46	33.18	*
624	61.65	V	-57.10	4.55	38.46	33.91	*
728	59.77	H	-57.20	2.57	32.97	30.40	*
728	59.59	V	-57.20	2.39	32.97	30.58	*
832	58.19	H	-57.20	0.99	28.85	27.86	*
832	58.22	V	-57.20	1.02	28.85	27.83	*
936	57.46	H	-57.20	0.26	25.64	25.38	*
936	57.94	V	-57.20	0.74	25.64	24.90	*
1040	56.31	H	-57.10	-0.79	23.08	23.87	*
1040	56.44	V	-57.10	-0.66	23.08	23.74	*

Note 1: * Indicates that measurements were below the noise floor of the measurement equipment and the reported value is the noise floor of the measurement system.

Note 2: The correction factor includes the antenna factors, cable loss, amplifier gains, and distance correction factor as discussed in Section 7.2.2.

[SUBSEQUENT TEXT REMOVED AS EXTRANEOUS]